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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/713,929 | 11/14/2003 | Gopi Venkatesh | 451194-101 | 4820 |

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Mark P. Levy, Esq., Thompson Hine. LLp
2000 Courthouse Plaza NE
10 W. Second Street
Dayton, OH 45402-1758

| EXAMINER |
|---|
| BARHAM, BETHANY P |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/12/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/713,929 | VENKATESH ET AL. | |
| | Examiner | Art Unit | |
| | Bethany P. Barham | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of the Applicants' Notice of Appeal filed on 1/16/2007 and After Final Amended Claims filed on 11/13/2007. Prosecution for this case is being reopened. Claims 1-11 and 24 are pending.

As a result of Applicants' amended claims and arguments, the *35 USC §102* US 4,839,177 rejections are hereby **withdrawn**.

## NEW REJECTIONS:

The following is a list of new rejections:

### *Claim Rejections – 35 USC §102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al US 2003/0215496 A1.

Patel et al teach the limitations of claims 1-7 and 24:

- Patel et al teaches a composition comprising muscle skeletal relaxants and cyclobenzaprine, salts, isomers and derivatives and mixtures thereof ([0036] and claim 24).
- Patel et al teaches compositions that can be provided in the form of a minicapsule, a capsule, tablet,....a pellet, a bead, etc [0168]. Examples 1-5 teaches how to prepare active ingredient coated beads.
- Pharmaceutical composition and/or the solid carrier particles taught by Patel et al can be coated with one or more enteric coatings, seal coatings, film coatings, barrier coatings, etc., and that the dosage form can be designed for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, synchronized release, or targeted delayed release [0169, col. 1]. Patel et al also teaches that the dosage form release profile can be affected by a polymeric matrix composition, a coated matrix composition, a multiparticulate composition, a coated multiparticulate composition, etc [0169, col. 2].
- The extended release coatings of Patel et al are preferably pH-independent coatings formed of, for example, ethyl cellulose [0172] and delayed release enteric coatings are acrylic polymers methacrylic acid copolymers, ammonio methacrylate copolymers, the Eudragit series E, L, S, RL, RS, NE and L-30D, and ethyl cellulose ([0184-0185], Example 8).

Patel et al teach the limitations of claims 8-9:

- Patel et al teaches that the coating can and usually does contain a plasticizer such as: triethyl citrate triacetin, acetyl triethyl citrate, polyethylene glycol 400, diethyl phthalate, tributyl citrate, acetylated monoglycerides, glycerol, fatty acid esters, propylene glycol and dibutyl phthalate [0189].

Patel et al teaches the limitations of claim 10-11:

- Patel et al teaches that various extended release dosage forms can be readily designed by one skilled in the art to achieve delivery to both the small and large intestines, to only the small intestine or to only the large intestine, depending on the choice of coating materials and/or coating thickness [0172].
- Extended release coatings of Patel et al also teach water soluble polymers such as hydroxypropyl cellulose, methylcellulose, hydroxymethyl cellulose, acrylic esters, etc. [0172].

Patel et al anticipates claims 1-11 and 24 of the instant application.

Claims 1-4, 6-11 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Meadows et al US 2003/0099711 A1.

Meadows et al teaches the limitations of claim 1-4, 6-7 and 24:

- Meadows et al teaches that the composition of their invention can be coated with a water-permeable diffusion barrier coating that is insoluble in gastrointestinal fluids thereby providing a controllable sustained release of drug and/or an enteric coating to formulate tailored release profiles [0001, 0009-0010, 0023]. Meadows

et al teaches that the invention provides therapeutic levels of the drug throughout the day and a controlled release drug preparation delivers drugs in a manner that will maintain therapeutically effective plasma levels over a period of time that is significantly longer than that which is given by a typical drug dosage form [0002].

- Meadows et al teaches that cyclobenzaprine is a suitable drug for their composition ([0029], col. 2 and claim 13).
- Meadows et al teaches coating with a diffusion barrier, preferably ethyl cellulose, such as Aquacoat or Surelease [0040, 0042-0043] and/or enteric coatings to allow the active ingredients to be released once the dosage has passed into the small intestinal tract [0046]. The enteric coating include copolymers of methacrylic acid and methyl methacrylate or ethyl acrylate, terpolymers of methacrylic acid, methacrylate, and ethyl acrylate [0047].
- Meadows et al teach that it is possible to tailor the drug release properties of the pharmaceutical preparation to provide a desired bioavailability profile, such as enteric coated free drug adsorbed on an inert substrate [0062-0067]. Meadows et al found that the enteric coated particles provide release in vivo of at least one drug over a period of about 4 hours, preferably over a period of 12 hours and more preferably the formulations of the present invention release in vivo at least one drug over a period of 24 hours [0070].

Meadows et al teaches the limitations of claim 8-9:

- Plasticizers are generally used for coating containing film-formers such as ethyl cellulose [0040]. Examples of suitable plasticizers for ethyl cellulose are dibutyl

sebacate, diethyl phthalate, triethyl citrate, tributyl citrate, triacetin, acetylated monoglycerides, phthalate esters, castor oil, etc. [0041].

Meadows et al teaches the limitations of claim 10-11:

- The optimum coat weight and thickness for barrier coating materials is taught by Meadows et al to be determined specifically for each drug-resin complex. For drug release from about 1-4 hours the coat weight is present in amount of about 10-20% by weight of the dry resin. For drug release from about 6-10 hours the coat weight is present in amount of about 30-35% by weight of the dry resin. Etc. Meadows et al teaches that the water-permeable, film-forming polymer comprises from about 1 to about 60% by weight of the drug-resin complex. For the enteric coating taught by Meadows et al it may be desirable to provide the coating directly onto the drug-resin complex or on a drug adsorbed on an inert substrate such as sugar spheres in the amounts of about 1.5- about 30%, preferably about 5- about 15% by weight of the particle being coated.
- Water-soluble substances are taught by Meadows et al as desirable to incorporate into the coating in order to alter permeability [0041]. Such substances are HPMC, HEC, methylcellulose or other cellulose polymers or mixtures of polymers [0040].

Meadows et al anticipates claims 1-4, 6-11 and 24 of the instant application.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on Monday – Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.P. Barham
Examiner-1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600